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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,780	02/10/2004	Keren I. Hulkower	06244.00002	9361

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EXAMINER	
VENCI, DAVID J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/775,780	HULKOWER ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *July 28, 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *137-142 and 148-153* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *137-142 and 148-153* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges Applicants' reply, filed July 28, 2005, which cancelled claims 143-147. Currently, claims 137-142 and 148-153 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 137-142 and 148-153 are rejected under 35 U.S.C. 102(b) as being anticipated by Humphries et al. (US 4,849,330).

Humphries et al. describe a device comprising an analyte-specific compound (see col. 8, line 47, "antibodies"), an analyte (see col. 8, lines 49-50, "ligands"), a detectable compound (see col. 9, line 41, "redox material"), a porphyrin dye (see col. 7, lines 53-54, "cytochrome C, and cytochrome b_2"), an enzyme conjugated to the analyte-specific compound (see col. 10, lines 56-57, "enzyme conjugated to... reciprocal binding pair member"), a substrate of the enzyme (see col. 10, line 51, "substrates"), a conjugate comprising an enzyme and a non-analyte-specific compound (see col. 9, lines 26-29, "label conjugated to... analyte analog"), a capture analyte-specific compound (see col. 11, line 12, "sandwich immunoassay"), a tracer comprising an analyte molecule bound to an enzyme (see col. 9, lines 26-29, "label conjugated to... analyte"), a receptor molecule (see col. 8, line 47, "antibodies"), and a sample (see col. 9, line 28, "sample").

Double Patenting

Claims 137-142 and 148-153 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 40 of U.S. Patent No. 6,495,102 in view of Humphries et al. (US 4,849,330).

U.S. Patent No. 6,495,102 claims a device (see e.g. claim 1, "nose") comprising at least one porphyrin dye (see e.g. claim 1, "porphyrin"). U.S. Patent No. 6,495,102 does not claim an analyte-specific compound, an analyte, a detectable compound, an enzyme conjugated to the analyte-specific compound, a substrate of the enzyme, a conjugate comprising an enzyme and a non-analyte-specific compound, a capture analyte-specific compound, a tracer comprising an analyte molecule bound to an enzyme, a receptor molecule, and a sample.

However, Humphries et al. describe a device comprising an analyte-specific compound (see col. 8, line 47, "antibodies"), an analyte (see col. 8, lines 49-50, "ligands"), a detectable compound (see col. 9, line 41, "redox material"), an enzyme conjugated to the analyte-specific compound (see col. 10, lines 56-57, "enzyme conjugated to... reciprocal binding pair member"), a substrate of the enzyme (see col. 10, line 51, "substrates"), a conjugate comprising an enzyme and a non-analyte-specific compound (see col. 9, lines 26-29, "label conjugated to... analyte analog"), a capture analyte-specific compound (see col. 11, line 12, "sandwich immunoassay"), a tracer comprising an analyte molecule bound to an enzyme (see col. 9, lines 26-29, "label conjugated to... analyte"), a receptor molecule (see col. 8, line 47, "antibodies"), and a sample (see col. 9, line 28, "sample").

Therefore, it would have been obvious for a person of ordinary skill in the art to modify the nose, as recited in claims 1 and 40 of U.S. Patent No. 6,495,102, by inserting various immunoassay components up it because Humphries et al. discovered a device providing "specific interactions" (see col. 4, line 64)

for detecting the presence of "specific components" (see col. 8, lines 33-34) in complex mixtures, such as urine (see col. 8, lines 40-42).

Claims 137-142 and 148-153 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 26 of copending Application No. 10/278421 in view of Humphries et al. (US 4,849,330), or alternatively, claims 1 and 21 of copending Application No. 10/279788 in view of Humphries et al. (US 4,849,330).

Application Nos. 10/278421 and 10/279788 claim a device (see e.g. claim 1, "nose") comprising at least one porphyrin dye (see e.g. claim 1, "porphyrin"). Application Nos. 10/278421 and 10/279788 do not claim an analyte-specific compound, an analyte, a detectable compound, an enzyme conjugated to the analyte-specific compound, a substrate of the enzyme, a conjugate comprising an enzyme and a non-analyte-specific compound, a capture analyte-specific compound, a tracer comprising an analyte molecule bound to an enzyme, a receptor molecule, and a sample.

However, Humphries et al. describe a device comprising an analyte-specific compound (see col. 8, line 47, "antibodies"), an analyte (see col. 8, lines 49-50, "ligands"), a detectable compound (see col. 9, line 41, "redox material"), an enzyme conjugated to the analyte-specific compound (see col. 10, lines 56-57, "enzyme conjugated to... reciprocal binding pair member"), a substrate of the enzyme (see col. 10, line 51, "substrates"), a conjugate comprising an enzyme and a non-analyte-specific compound (see col. 9, lines 26-29, "label conjugated to... analyte analog"), a capture analyte-specific compound (see col. 11, line 12, "sandwich immunoassay"), a tracer comprising an analyte molecule bound to an enzyme (see col. 9, lines 26-29, "label conjugated to... analyte"), a receptor molecule (see col. 8, line 47, "antibodies"), and a sample (see col. 9, line 28, "sample").

Therefore, it would have been obvious for a person of ordinary skill in the art to modify the tongue, as recited in claim 1 and 26 of Application No. 10/278421, or alternatively, claims 1 and 21 of copending Application No. 10/279788, by placing various immunoassay components on it because Humphries et al. discovered a device providing "specific interactions" (see col. 4, line 64) for detecting the presence of "specific components" (see col. 8, lines 33-34) in complex mixtures, such as saliva (see col. 8, lines 40-42).

These are provisional obviousness-type double patenting rejections.

Response to Arguments

In prior Office Action, claims 137-142 and 148-153 were rejected under 35 U.S.C. 102(b) as being anticipated by Humphries et al. (US 4,849,330). In response, Applicants argue that Humphries et al. do not teach a porphyrin dye which binds to a detectable compound. Applicants appear to argue that interactions involving heme porphyrin are limited to molecules belonging to "the cytochrome protein component" (see Applicants' reply, p. 7, lines 23-25).

Applicants' argument has been carefully considered but is not persuasive because Applicants' invention, as claimed, merely requires a "porphyrin dye" which binds a "detectable compound". Humphries et al. teach a porphyrin dye (see col. 7, lines 53-54, "cytochrome C, and cytochrome b_2") which binds a detectable compound (see col. 9, line 41, "redox material"). Applicants' position that interactions involving heme porphyrin are limited to molecules belonging to "the cytochrome protein component" does not appear to detract from the reality that Humphries et al. teach a porphyrin dye (see col. 7, lines 53-54, "cytochrome C, and cytochrome b_2") which binds a detectable compound (see col. 9, line 41, "redox material"). Thus, Humphries et al. fully meet the claimed limitations of Applicants' invention.

In prior Office Action, claims 137-142 and 148-153 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 40 of U.S. Patent No. 6,495,102 in view of Humphries et al. (US 4,849,330). In addition, claims 137-142 and 148-153 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 26 of copending Application No. 10/278421 in view of Humphries et al. (US 4,849,330), or alternatively, claims 1 and 21 of copending Application No. 10/279788 in view of Humphries et al. (US 4,849,330). In response, Applicants distinguish claims 137-142 and 148-153 of the instant application, which require indirect detection of analyte. As such, Applicants argue that the

combined teachings of U.S. Patent No. 6,495,102, or copending Applications No. 10/278421, or 10/279788 with Humphries et al. require "substantial reconstruction and redesign" and would require "a change in the basic principle" under which the devices of U.S. Patent No. 6,495,102, or copending Applications No. 10/278421, or 10/279788 were designed to operate.

Applicants' argument has been carefully considered but is not persuasive because the general operating principle underlying the invention of claims 137-142 and 148-153 of the instant application appear to be nearly identical compared to the general operating principle underlying the devices claimed in U.S. Patent No. 6,495,102, or copending Applications No. 10/278421, or 10/279788. Differences in analyte detection (i.e. indirect detection versus direct detection) appear minor such that persons of ordinary skill in the art would not have been precluded for any technical reason from combining the teachings of Humphries et al. to arrive at Applicants' claimed invention, but would have considered such a combination obvious for the reasons set forth supra.

Conclusion

No claims are allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

David J Venci
Examiner
Art Unit 1641

djv

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08/31/05